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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,821	12/21/2000	Daniel C. Carter	P06896US00/BAS	6567

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STITES & HARBISON PLLC
1199 NORTH FAIRFAX STREET
SUITE 900
ALEXANDRIA, VA 22314

EXAMINER	
LIU, SAMUEL W	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/740,821	CARTER, DANIEL C.	
	Examin r	Art Unit	
	Samuel W. Liu	1653	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 1955*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *39-44 and 47-49* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-43 and 47-49* is/are rejected.

7)☒ Claim(s) *44* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/15/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DTAILED ACTION

Status of claims

Claims 39-44 and 47-49 are pending.

The amendment filed 5/3/06 which cancels claims 1-38, amends claims 39, cancels claims 1-38 and 45-4, and adds claim 49 (drawn into the elected invention) has been entered. Also, the applicant's request (filed 5/3/06) for extension of time of five months has been entered.

The following Office action is applied to the pending claims 39-44 and 47-49.

Please note that grounds of objection and/or rejection not explicitly restated and/or set forth below are withdrawn.

IDS

The reference EP 0244859 in the IDS filed 10/15/02 is duplicated because the IDS filed 5/8/02 contains this reference, which has been considered by examiner.

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 39, 43 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Mausner, J. (US Pat. No. 5254331) as is evidenced by the fact that ascorbyl palmitate has surfactant property shown by Palma et al. (*Eur. J. Pharmaceut. Sci.* (2002) 16, 37-43).

In the patent claim 1, Mausner teaches a skin cream composition comprising human serum albumin (see item *i*). In the patent claim 3, Mausner teaches that said composition further comprises glyceryl arachidonate which acts as a surfactant-cleansing agent when applied to skin. Also, in Table I, Mausner teaches that said skin cream comprises ascorbyl palmitate, which acts like surfactant (Palma et al. reference) as well, wherein the surfactant, e.g., detergent is well-known cleansing agent absent factual indicia to the contrary (*note that soap is a surfactant, see the attachment*). The Mausner's teachings therefore anticipate instant claim 39.

On column 7, line 3, Mausner teaches that the protein complex comprises about 28% serum protein (note that the patent claim 1 sets forth that the serum protein is *human serum albumin*). In the patent claim 1, item *d*, Mausner teaches that the protein complex comprises about 6.9% of said composition, i.e., the human serum albumin comprises 1.9% of said composition which is resulted from calculation: 6.9% × 28% = 1.9%. The result 1.9% is equivalent to 1.9 g/100g, or approximately to 1.9 g per 100 ml of said skin *cream* composition, i.e., 19 mg/ml of the human serum albumin in said composition, which meets the limitation "1 to 250 mg/ml" of human serum albumin set forth in claim 43. Thus, the above Mausner's teaching anticipates instant claim 43.

The Mausner's composition is prepared in a cream form (see the claim 1), which anticipates instant claim 49.

Response to the rejection under USC 35 102(b)

On pages 2 and 3, the response filed 5/3/06 discusses the issue with regard to amount of skin cleansing agent, glyceryl arachidonate (GA) and ascorbyl palmitate (AP), and asserts that GA and AP may not necessarily function as a skin cleansing agent, and submits that small amounts of GA and/or AP cannot be acting as a cleansing agent; and thus, the response infers that Mausner does not disclose the cleansing composition comprising a cleansing agent in an amount effective to cleanse skin or hair (the 1st paragraph at page 3).

The applicants' argument is found to be unpersuasive because AP, as discussed above, is has surfactant property, and thus, it can act as a cleansing agent, furthermore, GA is a surfactant-cleansing agent used in cosmetics as is supported by the Eppler et al. reference (Eppler et al. abstract number 1594). The Mausner composition contains the cleansing agent glyceryl arachidonate ~ 0.7 to ~ 0.9%, i.e., about 1% glyceryl arachidonate. The response argues urges that this amount is insufficient for being a cleansing agent in the composition. Burke et al. (US Pat. No. 5693318) has taught a skin cleanse composition comprising 0.1 to 50 % surfactant (i.e., cleansing agent) (see column 2, line 33). Burden is shifted to applicants to show or prove that 1% cleanser agent, e.g., 1% GA, is not sufficient for the cleaning purpose.

In addition, the response argues that pure human serum albumin (HSA) is required in the instant invention while the Mausner composition comprises HSA protein with heterogeneous protein(s) which may interfere with absorption of HSA into skin, and thus, the response infers that Mausner teaches away from the human albumin composition as claimed.

The applicants' argument is found not persuasive because the independent claim 39 the claims dependent thereto do not recite that human serum albumin (HSA) is isolated/purified to pure form, and because the claim language (amended) "*consisting essentially of* ..." which is a

open-ended does not necessarily indicate that the claimed composition comprises pure HSA or purely purified HSA protein

The flowing is the new ground of rejection

Claims 39, 41-43 and 47 are rejected under 35 U.S.C. 102(a) as being unpatentable over Nielsen et al. (*Biochem. Biophys. Acta* (2000, June) 1479, 321-331), and in light of the fact that nickel metal is harmful for cosmetic preparation (Barczac, C. (1995) *The Hazards of Cosmetics*, pages 1-5); wherein sodium laureth sulfate taught by Nielson et al. has inherent property of acting as detergent cleansing agent shown by Paula Begoun-the cosmetics cop (2005) *Cosmetic ingredient dictionary, "sodium laureth sulfate"* section, page 2).

In "*Materials and methods*" section, Nielsen et al. teach a composition comprising a bovine serum albumin (BSA), and a detergent sodium laureth sulfate, wherein said detergent is dissolved in liquid buffer solution comprising 20 mM Tris, 100 mM NaCl at pH7.0. The composition is qualified for a cleansing composition since the sodium laureth sulfate is a detergent cleansing agent (see page 2 of the Paula Begoun-the cosmetics cop reference). The Nielsen et al. teachings are applied to instant claims 39, 41 and 47.

It is of note that the detergent cleansing agent is a kind of soap.

Nielsen et al. teach that the said albumin protein of 100 μM which is equivalent to 6.7 mg/ml (in view of BSA molecular weight is about 67,000 daltons) is dissolved in the solution comprising 4mM sodium laureth sulfate (i.e., ~ 1.15 mg/ml sodium laureth sulfate in light of molecular weight of sodium laureth sulfate is about 288 daltons), which is applied to instant claims 42-43.

Please note that "cleansing agent" has been given itself patentable weight in claim **39,** and that the current claim language as written is broadly drawn to encompassing any type of detergent cleansing agent. Also, note that the preambles "*for skin or hair*" after "composition", and "cleansing" before "composition" (claim 39, 38 and 40-44), and "hypoallergenic cleaning" before "composition" (claims 45-48) are considered to have little patentable weight. This is because structural feature is inherent property of a biomolecule; the above-stated functional preambles "cleansing" and "hypoallergenic cleansing" would not alter property/components of the claimed composition. It is of note that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Claim Rejections - 35 USC §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 39-40, 43 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mausner, J. (US Pat. No. 5254331) taken with Miller, D. G. (EP 0180968) and Maki et al. (US Pat. No. 5759802).

The rejection to claims 39, 43 and 49 has been discussed above.

Mausner does not expressly teach that the human serum albumin is recombinantly produced.

Maki et al. teach recombinantly produced human serum albumin (rHSA) and the detail process of expression/production of said rHSA. Also, Maki et al. teach the rHSA protein recombinantly produced (secreted) from host cells, e.g., yeast cells, is readily subject to conventional purification procedures (see column 11, line 46-64), as applied to instant claim 40.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the cleansing composition comprising rHSA which substitutes for naturally-occurring HSA. One skilled in the art would have been motivated to do this because of the following reasons.

Miller has taught that human serum albumin is particularly useful as a skin antiwrinkle agent (see abstract), and thus, the skilled artisan would have preferred to use serum albumin purified from human and formulated it in the cleansing composition.

Maki et al. have taught that the recombinant human serum albumin proteins produced from bacteria (e.g., *E.coli.*) are disadvantageous because the *E.coli.* expressed rHSA proteins

have amino acid sequence different from that of natural human serum albumin (see column 1, lines 14-27), i.e., the bacterial host unfaithfully produced the recombinant HSA protein. However, production of HSA in eukaryotic yeast transformant has no such the disadvantage. Maki et al. also have taught that their purification of rHSA needs less cost compared to other recombinant production of human serum albumin in that their rHSA proteins are first expressed as the secreted proteins and then purified by conventional protein purification (column 11, line 46-64, and Example 17). Also, the Mike et al. method has advantage that the recombinantly produced rHSA can be obtained in a large quantity (see column 2, line 21).

Thus, the skilled artisan would have produced rHSA according to the Mike's method and formulated into the Mausner's cleansing composition for skin or hair with successful expectation.

Therefore, the claimed invention was *prima facie* obvious to make and use the invention at the time it was made.

Claims 39-40, 41-43 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (*Biochem. Biophys. Acta* (2000, June) 1479, 321-331) taken with Miller, D. G. (EP 0180968) and Maki et al. (US Pat. No. 5759802).

The rejection to claims 39, 41-43 and 47 has been discussed above.

Yet, Nielsen et al. does not expressly teach that the serum albumin is recombinantly produced human serum albumin.

Maki et al. teach recombinantly produced human serum albumin (rHSA) and the detail process of expression/production of said rHSA. Also, Maki et al. teach the rHSA protein

recombinantly produced (secreted) from host cells, e.g., yeast cells, is readily subject to conventional purification procedures (see column 11, line 46-64), as applied to instant claims 40 and 48.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the cleansing composition comprising rHSA which substitutes for naturally-occurring HSA. One skilled in the art would have been motivated to do this because of the following reasons.

Miller has taught that human serum albumin is particularly useful as a skin antiwrinkle agent (see abstract), and thus, the skilled artisan would have preferred to use serum albumin purified from human and formulated it in the cleansing composition.

Maki et al. have taught that the recombinant human serum albumin proteins produced from bacteria (e.g., *E.coli.*) are disadvantageous because the *E.coli.* expressed rHSA proteins have amino acid sequence different from that of natural human serum albumin (see column 1, lines 14-27), i.e., the bacterial host unfaithfully produced the recombinant HSA protein. However, production of HSA in eukaryotic yeast transformant has no such the disadvantage. Maki et al. also have taught that their purification of rHSA needs less cost compared to other recombinant production of human serum albumin in that their rHSA proteins are first expressed as the secreted proteins and then purified by conventional protein purification (column 11, line 46-64, and Example 17). Also, the Maki et al. method has advantage that the recombinantly produced rHSA can be obtained in a large quantity (see column 2, line 21).

Thus, the skilled artisan would have produced rHSA according to the Maki's method and formulated into the Nielsen's composition.

Therefore, the claimed invention was *prima facie* obvious to make and use the invention at the time it was made.

NOTE: Claim 44 is objected to as being dependent upon a rejected base claim 39, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber, Jon, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

SWL

Samuel Wei Liu, Ph.D.
Patent Examiner, AU1653
July 7, 2006

JON WEBER
SUPERVISORY PATENT EXAMINER